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OP-1647  
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PATENT  
Attorney Docket No. MERCK-2056

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Hartmann *et al.*  
SERIAL NO.: 09/708,506 GROUP NO.: 1647  
FILING DATE: November 9, 2000 EXAMINER: DeBerry, Regina M.  
TITLE: ERYTHROPOIETIN FORMS WITH IMPROVED PROPERTIES

**CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8**

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 12<sup>th</sup> day of November, 2003.

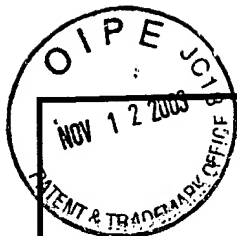
  
Malecia Allen

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith are:

1. Transmittal Form (1 page);
2. Fee Transmittal Form (1 page);
3. Supplemental Information Disclosure Statement (2 pages);
4. Form PTO-1449 (2 pages);
5. Copies of cited references A67-A81, B96-B106, and C182-C190;
6. A check in the amount of \$180.00; and
7. A return receipt postcard.



# TRANSMITTAL FORM

Application Serial Number	09/708,506
Filing Date	November 9, 2000
First Named Inventor	Hartmann
Group Art Unit	1647
Examiner Name	DeBerry, Regina M.
Attorney Docket No.	MERCK-2056
Patent No.	Not applicable
Issue Date	Not applicable

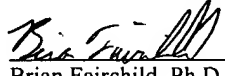
## ENCLOSURES (check all that apply)

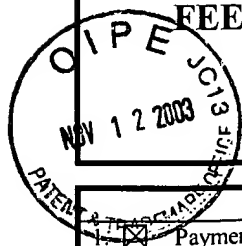
<input checked="" type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Check Attached <input type="checkbox"/> Copy of Fee Transmittal Form	<input type="checkbox"/> Copy of Notice to File Missing Parts of Application	<input type="checkbox"/> Notice of Appeal to Board of Patent Appeals and Interferences
<input type="checkbox"/> Amendment/Response <input type="checkbox"/> Preliminary <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets ____]	<input type="checkbox"/> Formal Drawing(s)	<input type="checkbox"/> Appeal Brief (in triplicate)
<input type="checkbox"/> Petition for Extension of Time	<input type="checkbox"/> Request For Continued Examination (RCE) Transmittal	<input type="checkbox"/> Status Inquiry
<input checked="" type="checkbox"/> Information Disclosure Statement <input checked="" type="checkbox"/> Form PTO-1449 <input checked="" type="checkbox"/> Copies of IDS Citations (A67-A81, B96-B106, and C182-C190)	<input type="checkbox"/> Power of Attorney (Revocation of Prior Powers)	<input checked="" type="checkbox"/> Return Receipt Postcard
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Certificate of First Class Mail
<input type="checkbox"/> Sequence Listing submission <input type="checkbox"/> Paper Copy/CD <input type="checkbox"/> Computer Readable Copy <input type="checkbox"/> Statement verifying identity of above	<input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application	<input type="checkbox"/> Certificate of Facsimile Transmission under 37 C.F.R. 1.8
	<input type="checkbox"/> Small Entity Statement	<input type="checkbox"/> Additional Enclosure(s) (please identify below)
	<input type="checkbox"/> CD(s) for large table or computer program	
	<input type="checkbox"/> Amendment After Allowance	
	<input type="checkbox"/> Request for Certificate of Correction <input type="checkbox"/> Certificate of Correction (in duplicate)	

## CORRESPONDENCE ADDRESS

Direct all correspondence to: Patent Administrator  
Testa, Hurwitz & Thibault, LLP  
High Street Tower  
125 High Street  
Boston, MA 02110  
Tel. No.: (617) 248-7000  
Fax No.: (617) 248-7100

## SIGNATURE BLOCK

Respectfully submitted,  
  
Date: November 12, 2003  
Reg. No. 48,645  
Tel. No.: (617) 248-7697  
Fax No.: (617) 248-7100  
Brian Fairchild, Ph.D.  
Agent for Applicants  
Testa, Hurwitz & Thibault, LLP  
High Street Tower  
125 High Street  
Boston, MA 02110



# FEE TRANSMITTAL FY 2004

Complete if Known

Application Serial Number	09/708,506
Filing Date	November 9, 2000
First Named Inventor	Hartmann
Group Art Unit	1647
Examiner Name	DeBerry, Regina M.
Attorney Docket No.	MERCK-2056

## METHOD OF PAYMENT

1. ☒ Payment Enclosed:  
☒ Check ☐ Money Order ☐ Other
2. ☒ The Commissioner is hereby authorized to credit or charge any fee indicated below for this submission to Deposit Account No. 20-0531.  
☐ Required Fees (copy of this sheet enclosed).  
☒ Additional fee required under 37 CFR 1.16 and 1.17.  
☒ Overpayment Credit.
3. ☐ Applicant claims small entity status.

## FEE CALCULATION

### 1. FILING FEE

#### Large Entity

Fee (\$)	Fee Description	Fee Paid
770	Utility filing fee	
340	Design filing fee	
160	Provisional filing fee	

Number Filed	Number Extra	Rate	Amount
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Total Claims - 20 = x \$ 18.00 =

Independent Claims - 3 = x \$ 86.00 =

☐ Multiple Dependent Claim(s), if any \$290.00 =

TOTAL:  
SMALL ENTITY DISCOUNT:  
SUBTOTAL (1) (\$) 0.00

### 2. AMENDMENT CLAIM FEES

Claims Remaining After Amend.	Highest No. Previously Paid For	Present Extra	Rate	Fee Paid
Total	-	=	x \$ 18.00 =	
Indep.	-	=	x \$ 86.00 =	
<input type="checkbox"/> First Presentation of Multiple Dep. Claim			+ \$290.00 =	

TOTAL: (\$)  
SMALL ENTITY DISCOUNT: (\$)  
SUBTOTAL (2) (\$) 0.00

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Entity Fee (\$)	Small Entity Fee (\$)	Fee Description	Fee Paid
130	65	Surcharge - late filing fee or oath	
50	25	Surcharge - late provisional filing fee or cover sheet	
130	130	Non-English specification	
2,520	2,520	Request for ex parte reexamination	
110	55	Extension for reply within first month	
420	210	Extension for reply within second month	
950	475	Extension for reply within third month	
1480	740	Extension for reply within fourth month	
2010	1005	Extension for reply within fifth month	
330	165	Notice of Appeal	
330	165	Filing a brief in support of an appeal	
290	145	Request for oral hearing	
130	130	Petitions to the Commissioner	
180	180	Submission of Information Disclosure Statement	180.00
770	385	Filing a submission after final rejection (37 CFR 1.129(a))	
770	385	For each additional invention to be examined (37 CFR 1.129(b))	
100	100	Certificate of Correction for applicant's error	
110	55	Submission of Terminal Disclaimer	
Other fee (Specify)			
Other fee (Specify)			

SUBTOTAL (3) (\$) 180.00

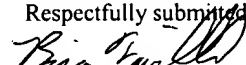
SUBTOTAL (1) 0.00  
SUBTOTAL (2) 0.00  
SUBTOTAL (3) 180.00

TOTAL (\$) 180.00

## CORRESPONDENCE ADDRESS

Direct all correspondence to:  
Patent Administrator  
Testa, Hurwitz & Thibault, LLP  
High Street Tower-125 High Street  
Boston, MA 02110  
Tel. No.: (617) 248-7000  
Fax No.: (617) 248-7100

## SIGNATURE BLOCK

Respectfully submitted,  
  
Brian Fairchild, Ph.D.  
Agent for the Applicants  
Testa, Hurwitz & Thibault, LLP  
High Street Tower-125 High Street  
Boston, MA 02110

Date: November 12, 2003  
Reg. No.: 48,645  
Tel. No.: (617) 248-7697  
Fax No.: (617) 248-7100



PATENT  
Attorney Docket No. MERCK-2056

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Hartmann *et al.* CONF. NO.: 2626  
SERIAL NO.: 09/708,506 GROUP NO.: 1647  
FILING DATE: November 9, 2000 EXAMINER: DeBerry, Regina M.  
TITLE: Erythropoietin Forms with Improved Properties

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

Additionally, Applicants wish to make the U.S. Patent and Trademark Office aware of the following patent applications: 09/292,217, filed April 15, 1999; 09/621,268, filed July 21, 2000; 10/419,058, filed April 18, 2003; 10/442,660, filed May 21, 2003; and 10/603,064, filed June 24, 2003.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☐ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or

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- ☒ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☒ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or
- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

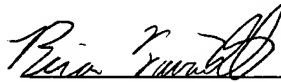
Applicants believe no additional fee is due for consideration of this submission. Nevertheless, if such a fee is required, please debit account 20-0531.

Date: November 12, 2003  
Reg. No. 48,645

Tel. No.: (617) 248-7697  
Fax No.: (617) 248-7100

2709181

Respectfully submitted,



\_\_\_\_\_  
Brian Fairchild, Ph.D.  
Agent for Applicants  
Testa, Hurwitz, & Thibault, LLP  
High Street Tower  
125 High Street  
Boston, Massachusetts 02110



FORM PTO - 1449

SUPPLEMENTAL  
INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: MERCK-2056

APPLICANTS: Hartmann *et al.*

SERIAL NO.: 09/708,506

CONF. NO.: 2626

FILING DATE: November 9, 2000 GROUP: 1647

## U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A67	6,617,135	9/9/03	Gillies et al.			
	A68	6,485,726 B1	11/26/02	Blumberg et al.			
	A69	6,475,717 B1	11/5/02	Enssle et al.			
	A70	6,335,176 B1	1/1/02	Inglese et al.			
	A71	2003/0166877 A1	9/4/03	Gillies et al.			
	A72	2003/0166163 A1	9/4/03	Gillies			
	A73	2003/0157054 A1	8/21/03	Gillies et al.			
	A74	2003/0105294 A1	6/5/03	Gillies et al.			
	A75	2003/0049227 A1	3/13/03	Gillies et al.			
	A76	2003/0044423 A1	3/6/03	Gillies et al.			
	A77	2002/0193570 A1	12/19/02	Gillies et al.			
	A78	2002/0192222 A1	12/19/02	Blumberg et al.			
	A79	2002/0147311 A1	10/10/02	Gillies et al.			
	A80	2002/0081664 A1	6/27/02	Lo et al.			
	A81	2001/0053539 A1	12/20/01	Lauffer et al.			

## FOREIGN PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B96	1 088 888 A1	4/4/01	EP					Y
	B97	WO 03/077834 A2	9/25/03	PCT					Y
	B98	WO 03/048334 A2	6/12/03	PCT					Y
	B99	WO 02/090566 A2	11/14/02	PCT					Y
	B100	WO 02/079415 A2	10/10/02	PCT					Y
	B101	WO 02/079232 A2	10/10/02	PCT					Y
	B102	WO 02/072605 A2	9/19/02	PCT					Y
	B103	WO 02/066514 A2	8/29/02	PCT					Y

EXAMINER

DATE CONSIDERED

<b>FORM PTO – 1449</b>				<b>ATTORNEY DOCKET NO.: MERCK-2056</b>					
<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b>				<b>APPLICANTS: Hartmann <i>et al.</i></b>					
				<b>SERIAL NO.: 09/708,506</b>			<b>CONF. NO.: 2626</b>		
				<b>FILING DATE: November 9, 2000 GROUP: 1647</b>					
<b>FOREIGN PATENT DOCUMENTS</b>									
<b>EXAM. INIT.</b>		<b>DOCUMENT NUMBER</b>	<b>DATE</b>	<b>COUNTRY CODE</b>	<b>CLASS</b>	<b>SUB CLASS</b>	<b>FILING DATE</b>	<b>ABSTRACT ONLY</b>	<b>ENGLISH LANG (Y/N)</b>
	B104	WO 02/02143 A2	1/10/02	PCT					Y
	B105	WO 01/58957 A2	8/16/01	PCT					Y
	B106	WO 01/36489 A2	5/25/01	PCT					Y
<b>EXAM. INIT.</b>	<b>OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)</b>								
	C182	Angal et al. (1993), "A Single Amino Acid Substitution Abolishes the Heterogeneity of Chimeric Mouse/Human (IgG4) Antibody," <u>Molecular Immunology</u> , 30:105-108.							
	C183	Bitoni et al. (2002), "Transepithelial Absorption of an Erythropoietin-Fc Fusion Protein After Delivery to the Central Airways," <u>Respiratory Drug Delivery</u> , 8:309-312.							
	C184	Darling et al. (2002), "Glycosylation of Erythropoietin Affects Receptor Binding Kinetics: Role of Electrostatic Interactions," <u>Biochemistry</u> , 41:14524-14531.							
	C185	Fibi et al. (1995), "N- and O-Glycosylation Muteins of Recombinant Human Erythropoietin Secreted From BHK-21 Cells," <u>Blood</u> , 85:1229-1236.							
	C186	Hammerling et al. (1996), "In vitro bioassay for human erythropoietin based on proliferative stimulation of an erythroid cell line and analysis of carbohydrate-dependent microheterogeneity," <u>Journal of Pharmaceutical and Biomedical Analysis</u> , 14:1455-1469.							
	C187	Kitamura et al. (1989), "Establishment and Characterization of a Unique Human Cell Line that Proliferates Dependently on GM-CSF, IL-3, or Erythropoietin," <u>Journal of Cellular Physiology</u> , 140:323-334.							
	C188	Locatelli et al. (2001), "Darbepoetin alfa Amgen," <u>Current Opinion in Investigational Drugs</u> , 2:1097-1104.							
	C189	Spiekermann et al. (2002), "Receptor-mediated Immunoglobulin G Transport Across Mucosal Barriers in Adult Life: Functional Expression of FcRn in the Mammalian Lung," <u>J. Exp. Med.</u> , 196:303-310.							
	C190	Syed et al. (1998), "Efficiency of signalling through cytokine receptors depends critically on receptor orientation," <u>Nature</u> , 395:511-516.							
<b>EXAMINER</b>					<b>DATE CONSIDERED</b>				